SECTION 5.0

Mantra International (HK) Ltd
1504 Vigor Industrial Building,
Block B, 20 Cheung Tat Road
Tsing Yi
Hong Kong
Tel: +852 2432 7181

JUL 30 2009

510(k) Summary

1. **General Information**

Trade Name of Device:	**"Mantra Combo"**
Common/Usual Name:	Transcutaneous Nerve Stimulator combined with Neuromuscular Stimulator
Classification Name:	Stimulator, Nerve, Transcutaneous for Pain Relief, Combined with Powered Muscle Stimulator
Submitters Name and Address:	Mantra International (HK) Ltd. 1504 Vigor Industrial bldg Block B, 14-20 Cheung Tat Road Tsing Yi, Hong Kong, China
Manufacturer:	Mantra International (HK) Ltd. 1504 Vigor Industrial bldg Block B, 14-20 Cheung Tat Road Tsing Yi, Hong Kong, China **Registration Number**: 3003741750

2. **Device Description**

The "**Mantra Combo**" combined TENS and NMS dual channel device is housed in small lightweight cabinet and is battery powered. The same circuitry is used to for both TENS and NMS.

3. **Indications for Use**

a. TENS: The device is intended for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post traumatic acute pain.

b. NMS: The device in recommended for use for the following conditions:
1. Relaxation of muscle spasms
2. Prevention of retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining and increasing range of motion.

4. Substantial Equivalence

This product is substantially equivalent to the Mantra TENS Model NT3 (K041520) Combined with the Classic NMS™ manufactured by Care Rehab Inc of McLean Virginia (K021905). The device is physically identical to both the Mantra TENS NT3 and Classic NMS™ consisting of exactly the same cabinet, PCB and circuitry. The TENS functionality (Modes and programs) of the Mantra COMBO is identical the Mantra NT3 TENS and the NMS functionality (modes and programs) is identical that of the Classic NMS™. Since the Classic NMS™ is also produced by Mantra International Ltd, all the technical characteristics, (including lead wires) are identical. The user can select either TENS or NMS modalities. In this way it is simply "two products in one".

5. Performance Studies

Performance testing was conducted on the "Mantra Combo" combined TENS & NMS device to demonstrate the integrity, suitability and substantial equivalence of the device

6. Conclusion

Based upon the Indications for use and performance studies the "Mantra Combo" has been shown to be substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Mantra International, Ltd.
c/o Mr. Brent Reider
President, International Trade Group, Inc.
4663 Kate Lane
Oxford, OH 45056

Re: K091236
Trade/Device Name: Mantra Combo
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ
Dated: July 2, 2009
Received: July 7, 2009

Dear Mr. Reider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k091236

Device Name: ***Mantra Combo*** (Combined TENS & NMS device)

Indications For Use:

a. TENS: The device is intended for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post traumatic acute pain.

b. NMS: The device is recommended for use for the following conditions:
1. Relaxation of muscle spasms
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Prescription Use X AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

07/20/09

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number k091236